



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-0913]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; 513(g) Request for Information

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202-395-7285, or emailed to oir_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0705. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-8867, PRASStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

513(g) Request for Information

OMB Control Number 0910-0705--Extension

This information collection supports Agency regulations and accompanying guidance. Section 513(g) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360c(g)) provides a means for obtaining the Agency's views about the classification and regulatory requirements that may be applicable to a particular device. Section 513(g) provides that, within 60 days of the receipt of a written request of any person for information respecting the class in which a device has been classified or the requirements applicable to a device under the FD&C Act, the Secretary of Health and Human Services shall provide such person a written statement of the classification (if any) of such device and the requirements of the FD&C Act applicable to the device. Regulations governing medical device classification procedures are codified under 21 CFR part 860.

The guidance document entitled "FDA and Industry Procedures for Section 513(g) Requests for Information Under the Federal Food, Drug, and Cosmetic Act; Guidance for Industry and Food and Drug Administration Staff" establishes procedures for submitting, reviewing, and responding to requests for information respecting the class in which a device has been classified or the requirements applicable to a device under the FD&C Act that are submitted in accordance with section 513(g) of the FD&C Act. FDA does not review data related to substantial equivalence or safety and effectiveness in a 513(g) request for information. FDA's responses to 513(g) requests for information are not device classification decisions and do not

constitute FDA clearance or approval for marketing. Classification decisions and clearance or approval for marketing require submissions under different sections of the FD&C Act.

Relatedly, the FD&C Act, as amended by the Food and Drug Administration Amendments Act of 2007 (Pub. L. 110-85), requires FDA to collect user fees for 513(g) requests for information. The guidance document entitled “Guidance for Industry and Food and Drug Administration Staff; User Fees for 513(g) Requests for Information” assists FDA staff and regulated industry by describing the user fees associated with 513(g) requests. The Medical Device User Fee Cover Sheet (Form FDA 3601), which accompanies the supplemental material described in this information collection is approved under OMB control number 0910-0511.

In the *Federal Register* of November 21, 2017 (82 FR 55381) FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received in response to the notice.

We therefore retain the currently approved burden estimate for the information collection, which is as follows:

Table 1.--Estimated Annual Reporting Burden¹

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
CDRH 513(g) requests	114	1	114	12	1,368
CBER 513(g) requests	4	1	4	12	48
Total					1,416

¹There are no capital costs of operating and maintenance costs associated with this collection of information.

Respondents to the collection of information are mostly device manufacturers; however, anyone may submit a 513(g) request for information. The total number of annual responses is based on the average number of 513(g) requests received each year by the Agency.

Dated: April 12, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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